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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Request for Information and Comments on the 2005 Public Health Service Policies on Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Request for Information (RFI).

SUMMARY: The Department of Health and Human Services (HHS), Office of Research Integrity (ORI) seeks the perspectives of individuals, research funding agencies, institutional officials, organizations, institutions, and other members of the general public on the 2005 Public Health Service Policies on Research Misconduct to help structure ORI's future plans to revise the regulation. To this end, ORI issues this RFI to collect input on the current regulation (see details in SUPPLEMENTARY INFORMATION section).

DATES: Responses to the RFI must be received electronically no later than 5:00 p.m. ET on October 31, 2022. Mailed paper submissions and submissions received after the deadline will not be reviewed.

ADDRESSES: Comments must be submitted electronically to OASH-ORI-Public-Comments@hhs.gov. Include "Regulations RFI" in the subject line of the email.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: ORI oversees and directs Public Health Service (PHS) research integrity activities on behalf of the Secretary of HHS, with the exception of the regulatory research integrity activities of the Food and Drug Administration (FDA). ORI's

mission is to protect science and public health and to conserve public funds by ensuring the integrity of all PHS-supported biomedical and behavioral research.

The Public Health Service Policies on Research Misconduct, 42 CFR parts 50 and 93, established several requirements regarding the handling of allegations of possible research misconduct and fostering of an environment that promotes research integrity and discourages research misconduct. Institutions receiving funding for research from any of the PHS funding components[1] must adhere to these requirements to receive PHS funding.

ORI conducts oversight of institutional research misconduct proceedings (inquiries and investigations) as well as institutional compliance with the PHS Policies on Research Misconduct at 42 CFR part 93. ORI also conducts outreach and develops educational resources that aid institutional efforts "to teach the responsible conduct of research, promote research

[1]PHS funding components are "any organizational unit of the PHS authorized to award grants, contracts, or cooperative agreements for any activity that involves the conduct of biomedical or behavioral research, research training or activities related to that research or research training, e.g., agencies, bureaus, centers, institutes, divisions, or offices and other awarding units within the PHS." 42 CFR 93.209. This includes the: National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), FDA, Substance Abuse and Mental Health Services Administration (SAMHSA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), Agency for Healthcare Research and Quality (AHRQ), Agency for Toxic Substances and Disease Registry (ATSDR), Office of the Assistant Secretary for Health (OASH), and Administration for Strategic Preparedness and Response (ASPR).

integrity, prevent research misconduct, and … respond effectively to allegations of research misconduct….” 65 FR 30600, 30601 (May 12, 2000).

The Public Health Service Policies on Research Misconduct (42 CFR part 93)[2] became effective in June 2005, replacing the Responsibilities of Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science (42 CFR part 50), which was promulgated in August 1989. ORI contemplates beginning a regulatory revision process for the 2005 ORI regulation at 42 CFR part 93 in the near future, using conventional rulemaking processes and channels for public notification and comment.

Input on the 2005 Public Health Service Policies on Research Misconduct

ORI seeks the perspectives of individuals, research funding agencies, institutional officials, organizations, institutions, and other members of the general public to help structure ORI’s future work toward an updated regulation. To this end, ORI issues this RFI to collect input on the current regulation at 42 CFR part 93.

ORI is not seeking specific regulatory language at this time, only the identification of potential topic(s), issue(s), or area(s) that stakeholders and other members of the general public see as being important to consider when revising the 2005 ORI regulation at 42 CFR part 93. Responders may find it helpful to consider the following questions when preparing responses (the order of the questions below should not be taken to imply importance, priority, or precedence):

1) Which section(s) should be changed or augmented when revising 42 CFR part 93? Why? How should the section(s) be changed or augmented?

[2]Hereafter referred to as the “2005 ORI regulation at 42 CFR part 93.”

2) Which section(s) should be retained as it currently is in 42 CFR part 93? Why?

3) Which section(s) should be considered for removal when revising 42 CFR part 93? Why?

ORI views this RFI as a brainstorming process. Short responses, limited to just a few words on a given topic, issue, or area will facilitate the organization and categorization of responses. If an idea specifically relates to a part of the current regulation, citing that section (e.g., § 314.3) would be helpful.

Collection of Information Requirements

Please note: This RFI is issued solely for information and planning purposes. It does not constitute a solicitation for: Request for Proposals (RFPs), applications, proposal abstracts, or quotations. This RFI does not commit the U.S. Government to contract for any supplies or services or to make a grant award. Further, ORI is not seeking proposals through this RFI and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in responding to this RFI; all costs associated with responding to this RFI will be solely at the expense of the responding parties. ORI notes that not responding to this RFI does not preclude participation in future conventional rulemaking concerning 42 CFR part 93. It is the responsibility of the potential responders to monitor this RFI announcement for additional information pertaining to this request.

ORI will actively consider all input received as our office initiates the rule making process in the near future. ORI may or may not choose to contact individual responders. Such communications would be for the sole purpose of clarifying statements in the responders' written responses. Responses to this notice are not offers and cannot be accepted by the U.S. Government to form a binding contract or to issue a grant. Information obtained from this RFI may be used by the U.S. Government on a non-attribution basis. Responders should not include any information that

might be considered proprietary or confidential. This RFI should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned.

Dated: August 29, 2022,

Wanda K. Jones,

Acting Director, Office of Research Integrity,

Office of the Assistant Secretary for Health.

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